

October 8, 1998

Mr. James M. Owendoff
Acting Assistant Secretary for
Environmental Management
Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585-1000

Dear Mr. Owendoff:

The Defense Nuclear Facilities Safety Board (Board) has examined the recent draft of Department of Energy (DOE) Order 435.1, *Radioactive Waste Management*, and its associated manual, guidance, and technical basis documentation. The enclosed comments are provided for your review and consideration.

With certain notable exceptions, the Order and its associated manual address reasonably well general requirements for the management of radioactive wastes. However, the guidance documents are too vague in many instances, and do not allow for uniform implementation of safety-related measures in all instances. For example, important safety issues, including venting of transuranic waste drums, storage of pyrophoric materials as waste, storage of wastes in areas not designed for waste storage, actions related to leaky tank systems, and conditions necessary to allow continued use of single-wall tank systems for high-level waste, are inadequately addressed. Additionally, requirements and guidance necessary to address issues raised by Board Recommendation 94-2 are inadequately covered or missing. This includes guidance for performance assessment (PA) and composite analysis (CA), and for changes made to the requirements for PAs and CAs.

The Board believes the guidance needs to be appropriately revised in both focus and scope so that a more concise, clear, and accurate document can be provided for review. In addition, the objective paragraph of the Order should be modified to clearly reflect DOE's intention to manage radioactive waste generation, treatment, storage, and disposal as a continuum, consistent with the principles currently embodied in the management of nonradioactive hazardous wastes. Waste management is to begin with design using waste minimization as an objective. These principles include: (1) incorporating radioactive waste management concerns into facility design; (2) emphasizing pollution prevention where feasible; (3) encompassing treatment and recycling where beneficial; (4) ensuring that all of DOE is responsible for the cradle to grave management of radioactive wastes, including safe interim storage and environmentally sound disposition. These principles should also be reflected in the accompanying documents making up this directive as well as in companion directives (e.g., DOE Order 420.1, *Facility Design* and DOE Order 430.1, *Life Cycle Assets Management*).

The Board has designated Mr. Steven Stokes to lead the review effort by the Board's staff and to continue technical dialogue with the DOE developer of this Order. If you have questions on this matter, please do not hesitate to call me.

Sincerely,

John T. Conway
Chairman

c: Mr. Mark B. Whitaker, Jr.

Enclosure

General Requirements

Reference	Status	Comment
General	Major	<p>The Department of Energy (DOE) defines Low-Level Waste (LLW) in draft Order 435.1 (June 25, 1998) to include accelerator-produced waste. Although accelerator-produced waste is not LLW, DOE may treat this waste as LLW so long as such treatment also meets statutory and regulatory requirements applicable to accelerator-produced waste. Since accelerator-produced waste is not LLW, these requirements are not to be found in the Atomic Energy Act or the Low Level Radioactive Waste Policy Act and associated regulatory structure. Rather, these requirements will be found under state and federal environmental laws, possibly the Resource Conservation and Recovery Act (RCRA) (depending on the actual nature of the waste material) or one of the many state RCRA-like statutes.</p> <p>Neither the draft Order nor the draft Manual, DOE M 435.1, June 27, 1998, make this distinction, even though the Manual provides specific performance objectives. (The Manual also introduces Naturally Occurring Radioactive Material (NORM) as LLW, which raises the same issue as accelerator-produced radioactive material. <i>See</i> Chapter IV, section B.(1).) In contrast to the Order and the Manual, The Guide, DOE G 435.1, section IV.A, June 29, 1998, states that “Commercial accelerator-produced waste is regulated in accordance with State laws,” but adds that state laws have not addressed accelerator-produced waste; therefore, DOE treats it as LLW to protect public health and safety. State law may or may not address this waste, depending on the state, but a state Conference of Radiation Control Program Directors has developed model regulations to address these problems. Also, RCRA may apply to the waste, depending on its characteristics.</p> <p>The Order and Manual should acknowledge the different nature of accelerator-produced waste and NORM (as compared to statutory LLW), and caution the reader to ensure state and RCRA requirements are met.</p>

General Requirements

Reference	Status	Comment
DOE M 435.1, I.B	Major	<p>The Manual states, “Additional information supporting the requirements in this Manual is contained in the Implementation Guide for use with DOE O 435.1, <i>Radioactive Waste Management</i>. This Guide, DOE G 435.1, <i>Implementation Guide for DOE M 435.1</i>, shall be reviewed when implementing the requirements of this Manual. The Guide provides suggestions and acceptable ways of meeting the requirements. Other methods may be used but shall be identified and the rationale for their use shall be documented.”</p> <p>The guidance contains several instances where the guidance is not sufficiently detailed to determine acceptable ways of meeting the requirements. For example, the guidance related to using the data quality objectives (DQO) process does not specifically identify the Environmental Protection Agency (EPA) guides associated with DQO’s as the acceptable method for using the process. More specificity should be provided in this case as well as others, e.g., more specific guidance related to Performance Assessments (PA) and Composite Analysis (CA), etc.</p>

High-Level Waste

Reference	Status	Comment
General	Major	The Order and Manual require that programs and processes be created to safely manage high-level waste (HLW), but they do not define the required elements of the programs and processes well enough to ensure that waste management will be conducted safely. Specific examples are listed in the detailed comments that follow, including lack of definition of processes for evaluating continued use of singly-contained HLW systems or continued use of HLW systems with breached containment.
DOE O 435.1, 3.B.1	Major	The definition of HLW should say what constitutes a “sufficient” concentration of fission products.
HLW Crosswalk	Major	<p>Elimination of the following requirements from 5820.2A was not justified:</p> <ul style="list-style-type: none"> - activity limit for routine transfers through single-wall pipelines I.3.b(2)(b) - segregation of sludge, salt, high/low activity wastes I.3.b(2)(e) - design, calibration, and testing of cathodic protection systems I.3.b(2)(g) - HLW storage at lower pressure than ancillary systems I.3.b(2)(h) - control of treatment reagents I.3.b(7)(d) - assessment of processes that can change the waste I.3.b(7)(e) - restriction against storing fresh HLW in single shell tanks (SSTs) except in emergency I.3.c(2)(a) <p>These requirements should be included or their termination justified.</p>
HLW Crosswalk	Major	Specific requirements are needed to detail what needs to be done to allow continued use of single-wall and leaking tanks, since DOE has so many. The vague requirements from 5820.2A I.3.b(4)(a) were deleted. The stated justification that it is adequate to generically require assessment of existing systems is inadequate.
HLW Crosswalk	Major	If there is no requirement in another document, the requirement to remediate releases should be retained (I.3.b(4)(b)). The argument that the existence of programs to prevent leaks makes it unnecessary to be ready to respond to a leak is unconvincing.

High-Level Waste

Reference	Status	Comment
HLW Crosswalk	Major	It's not clear that the Code of Federal Regulations (CFR) referenced in II.T.1 require monitoring wells, as implied by the crosswalk (5820.2A I.3.c(3)(d), I.3.b(3)(f)).
HLW Crosswalk	Major	The requirement for trained personnel should apply to design and operation of non-safety related structures, systems, and components (435.1 I.1.E(11)).
DOE M 435.1, II.A	Major	The definition of HLW should say what constitutes a "sufficient" concentration of fission products.
DOE M 435.1, II B.2	Major	This should be clarified to say that items a, b, and c all need to be met to allow classifying waste as "incidental."
DOE M 435.1, II B.2.a	Major	The process for deciding what amount of radionuclide removal is "technically and economically practical" should be defined in the Manual.
DOE M 435.1, II	Major	Reference to the CFR that defines what the "key radionuclides" are should be added to the Manual. (It's currently only in the Guide.)
DOE M 435.1, II.B.2.a	Major	Only treated HLW (not HLW that <u>will be</u> treated) ought to be eligible for consideration as incidental waste.
DOE M 435.1, II.F	Major	The waste management basis as defined here consists only of waste acceptance criteria and waste certification criteria. These two elements do not constitute a complete waste management basis.
DOE M 435.1, II.H.1	Major	Contingency storage ought to be required to meet all the same requirements as normal HLW storage, e.g., leak detection, instrumentation, ventilation, double containment, etc. The Guide states that railcars and tanker trucks may be used, but they do not appear to meet all the requirements for a HLW storage facility.
DOE M 435.1, II.H.1	Major	Separate contingency storage capacity should be provided for incompatible waste types. (This is suggested in the Guide, but not required in the Manual.)

High-Level Waste

Reference	Status	Comment
DOE M 435.1, II.J	Major	The only real requirement for the waste acceptance criteria is that the HLW facility can only receive HLW, without approval of an exception. The Manual should require a waste acceptance criterion to ensure incoming wastes can be safely handled at the facility.
DOE M 435.1, II.J.1.c	Major	Ultimate compliance with disposal criteria should be a system objective, not a waste acceptance criterion.
DOE M 435.1, II.K.2	Major	Limits should be specified for generation of waste that has no path forward to disposition. As now written, any type of waste, in any quantity, and with any number of problematic characteristics is acceptable, if approved.
DOE M 435.1, II.K.2	Major	The plan for creating a path forward to disposal should be required as a precursor to generating waste with no path forward, not just a suggestion in the Guide.
DOE M 435.1, II.L	Major	Requiring characterization “in sufficient detail” does not provide adequate definition of what must be done. The level of detail should be more prescriptive.
DOE M 435.1, II.L.1	Major	References for the DQO process are needed if they aren’t given elsewhere in the Manual.
DOE M 435.1, II.L.2.a and II.L.3	Major	What specific physical and chemical characteristics are needed (e.g., phase, flammability, mass, concentration, pH, vapor pressure)?
DOE M 435.1, II.L.4	Major	The requirement that process knowledge “shall” be used instead of analytical results sounds like the sites are not allowed to sample the wastes and is inappropriate.
DOE M 435.1, II.P.1(b)	Major	What is “adequate protection”? Should there be a reference document here?
DOE M 435.1, II.P.2(b)(2)	Major	Include in this section a description of what needs to be done to permit use of an HLW system without secondary containment. This should address what needs to be done as compensatory measures to allow continued use of leaking tanks.

High-Level Waste

Reference	Status	Comment
DOE M 435.1, II.P.2(h)	Major	The key elements of the structural integrity program (e.g., modeling, monitoring, maintenance, etc.) should be called out in the Manual. Consistent with the sections on waste acceptance and waste characterization, the required minimum elements of an effective program should be a requirement in the Manual.
DOE M 435.1, II.U.2	Major	Closure of facilities that contain non-incidental waste residuals ought to be approved by the appropriate DOE official, not just the Nuclear Regulatory Commission.
DOE G 435.1, II. A	Major	Definition of High-Level Waste—The discussion of spent fuel is incomplete and needs to address irradiated fuel that may be reprocessed using methods not meeting the traditional definition of reprocessing. For example, the baseline strategy for processing K-Basin sludge will be used to treat small pieces of spent fuel but the methods employed are not those traditionally associated with reprocessing. The definition of high-level waste should address which materials from such a process will be allowed to be transuranic waste, low-level waste etc. In addition, other processing methods not meeting the definition of reprocessing have been contemplated for disposition of Spent Nuclear Fuel (SNF) at both the Idaho National Engineering and Environmental Laboratory and Savannah River Site (SRS). Since the K-Basins experience does not appear to be an isolated case, the Order needs to address all categories of wastes using non-traditional forms of reprocessing.
DOE G 435.1, II.B.2(a)	Major	The process described here for determining how much of the key radionuclides need to be removed to turn HLW into incidental waste is not adequate.
DOE G 435.1, II.I	Minor	Corrective Actions—There should there be a reference for an Order or standard to follow that defines the procedure to identify, document, and resolve deficiencies?
DOE G 435.1, II.J	Major	Waste Acceptance—The detailed review of data should also include chemical analysis in addition to radioanalysis. (pg. 52)
DOE G 435.1, II.J	Major	Waste Acceptance—The use of audits and surveillance of the waste generator's processes and certifications program should not be the sole determinant in accepting waste. For example, review of the characterization program should also be required. (pg. 52)

High-Level Waste

Reference	Status	Comment
DOE G 435.1, II.L	Major	The paragraphs discussing procurement, document control, and training for characterization are unnecessary. These pieces of guidance should apply to the entire waste management effort, not just HLW characterization. (pg. 60)
DOE G 435.1, II.L	Major	The top of this page discusses how sampling may not be warranted if the risk of simply accepting uncertainty in waste characterization is judged to be less significant than the worker hazard and potential programmatic delays associated with sampling operations. The wording understates the need to ensure that the risk associated with uncertain characterization is minimal, and overstates the importance of programmatic delays relative to immediate safety issues. This section should point out that re-engineering sampling operations to reduce worker hazards should be considered in the suggested documented trade-off analysis. (pg. 63)
DOE G 435.1, II.L	Major	The guidance states that a graded approach should be taken to the DQO process based on the importance of the characterization data in terms of environmental and worker hazards. This is unnecessary and confusing, because the DQO process embodies a graded approach in its requirement that the user identify what waste properties are important and the amount of uncertainty that is acceptable. (pg. 68)
DOE G 435.1, II.M	Major	The paragraphs discussing procurement, document control, and training for waste certification are unnecessary. These pieces of guidance should apply to the entire waste management effort, not just HLW certification. (pg. 76)
DOE G 435.1, II.M	Major	It is not clear what is meant by the statement that a graded approach should be used for the waste certification program. Further guidance is needed to explain what characteristics of the waste should be used in determining how to apply a graded approach, and what elements of the certification program can be omitted or reduced in rigor as part of the graded approach. (pg. 78)
DOE G 435.1, II.P.1	Major	The discussion of environmental factors for HLW facility siting should provide guidance on how to assess the factors listed, such as flora and fauna, and should also provide acceptance criteria for this evaluation. (pp. 101-103)

High-Level Waste

Reference	Status	Comment
DOE G 435.1, II.P.1	Major	Including a canceled Order (6430.1A) in the list of supplemental references is of questionable value. (pg. 105)
DOE G 435.1, II.P.2	Major	The discussion of hazard analyses, safety analyses, and technical safety requirements (TSRs) should clearly explain how to implement the Orders that are referenced here. Also, pg. 110 states that TSRs are generally only used for safety class systems that are needed to protect the public, whereas pg. 111 states that TSRs should be used to protect workers and provide defense-in-depth. These statements should be made consistent. (pp. 109-111)
DOE G 435.1, II.P.2	Major	The repeated references to the “DOE Evaluation Guidelines” should be tied to a specific document that defines what these guidelines are. (pg. 110)
DOE G 435.1, II.P.2.(b)(2)	Major	Guidance should be provided for how to determine whether or not a HLW tank system with no secondary containment is fit for use. This guidance should include specific criteria for determining if the tanks system can be used, i.e., risk based criteria that could be used to determine if the tank system is adequate to protect the workers and the public. [note: The existing guidance essentially states that if the tank is not currently leaking or if it is covered by an authorization basis, it is acceptable. These attributes do not provide sufficient justification for allowing unrestricted use of a tank with no secondary containment.] (pg. 118)
DOE G 435.1, II.P.2(d)	Major	This section states that a “graded approach” should be applied to the requirement that ventilation systems provide adequate filtration to keep releases below applicable limits. The use of the term “graded approach” is not appropriate in this instance. For example, the ventilation system must simply be adequate to protect the workers and the public by meeting the applicable design standards and/or health standards. (pg. 125)
DOE G 435.1, II.U.2.(a)	Major	The guidance ought to explain what partial closure is. (pg. 164)

Transuranic Waste

Reference	Status	Comment
General	Major	The level of detail of the requirements remains too shallow. Despite the large volume of guidance material, specificity of requirements remains deficient due to the process orientation of the documentation. As a result, certain safety related issues (see specific findings below) which the staff believes should be mandatory requirements are either not covered or appear as suggestions in the guidance document. <i>The specific safety requirements described below should not be discretionary.</i>
General	Major	There is no mandatory complex-wide requirement for the early installation of vents in drums and boxes of <u>contact handled transuranic (TRU) wastes or for those drums and boxes of LLW having the capability of becoming pressurized</u> . There are only suggestions in the Guidance Document (see p. III-60). This is not acceptable considering the number of examples found in the occurrence reporting system of safety problems involving pressurized drums and boxes. In addition, in the case of TRU wastes, the vast majority of which is intended for disposal at Waste Isolation Pilot Plant (WIPP), venting is a WIPP waste acceptance criteria (WAC) requirement. Furthermore, venting of all TRU waste Type A packages is a requirement of the existing 5820.2A Order intended to be superseded by this draft Order. For all these reasons, DOE should specify an appropriate mandatory venting requirement from the time a container is initially filled for <u>all</u> contact handled (CH) TRU waste drums and boxes and for all LLW containers potentially subject to gas or vapor pressurization. In addition, the Order should establish a mandatory schedule following implementation of the Order for completion of vent installation on all backlog drums either intended for WIPP or subject to potential pressurization. Case-by-case exceptions to venting requirements can be provided for non-gas generating CH TRU wastes not intended for disposal at WIPP and for those containers of LLW which are sufficiently characterized to assure that they do <u>not</u> contain materials that could generate potentially pressurizing gasses or vapors, and for wastes which must be temporarily stored in locations where, due to lack of protection from the weather, the presence of a vent would allow the introduction of water into the container. There should also be mandatory requirements for the handling and storing of potentially pressurized unvented backlog drums until they are brought into compliance. Such requirements should include the use of safety nets and grape presses or similar equipment to preclude loss of container integrity prior to vent installation.

Transuranic Waste

Reference	Status	Comment
General	Major	Storage of reactive metals (e.g., uranium) in contact with water (e.g., Y-12 stores wet depleted uranium saw fines in unvented drums) should be prohibited.
General	Major	Storage of pyrophoric materials should be prohibited (i.e., U, Th, and Pu metal turnings, other materials that can form hydrides, e.g., both Fernald Environmental Management Project and Rocky Flats Environmental Technology Site (RFETS) store uranium metal chips, fines, etc.). [Proposed requirement is weaker than existing 5820.2A requirement and is not a prohibition but only requires packaging of pyrophoric materials to prevent ignition.]
General	Major	Storage of dried ion exchange resins should be prohibited.
General	Major	Storage of cellulosic material contaminated with concentrated nitric acid should be prohibited.
General	Major	Storage of containers holding volatile materials in areas subject to high temperatures should be prohibited.

Transuranic Waste

Reference	Status	Comment
General	Major	<p>Storage facility requirements that should be mandatory include:</p> <ul style="list-style-type: none"> (a) Waste must be stored <u>only</u> in areas specifically designed for waste storage unless a temporary “emergency” exception has been granted (i.e., waste should not be stored around gloveboxes, tanks, offices, or other high traffic areas, e.g., at RFETS operators had to stand by rows of drums each containing 1000 g Pu to drain a tank through a glovebox). (b) Storage pads must be covered and protected from the environment. The Order should establish a schedule with dates following implementation of the Order by which all unprotected storage has been eliminated. For example, Fernald had drum corrosion problems when storing drums on uncovered storage pads and in buildings with roof leaks. Additionally, drums at SRS are stored in metal warehouses with roof leaks, broken windows, and gaps that allow mud to enter the building and cover the floor and drums. (c) Containers must be stored in a configuration that allows inspections of container condition to be performed—no close packed arrays. The current guidance (III-116) suggests “phasing out” such close packed storage “to the extent practical” but does not mandate it or set deadlines for phase out to be accomplished. The order should establish a schedule with dates following implementation of the Order by which all reconfiguration of storage must be completed. (d) In addition to facility safety analyses, fire hazards analyses should be required for waste storage facilities storing combustible wastes. This is especially important for drums. stored in a location that allows an unfiltered release (e.g., docks, Butler buildings).

Low-Level Waste

Reference	Status	Comment
General	Major	Guidance for the format and content of a performance assessment and/or composite analysis is not present. In previous revisions of DOE Order 5820.2A these components were present. This guidance is a critical part of the directive and needed to meet the intent of the Board's Recommendation 94-2 and should be included.
DOE G 435.1, IV. D	Major	The guidance states that the radioactive waste management basis for LLW disposal facilities is based upon controls imposed by the performance assessment and composite analysis. It is not clear what these are since there is no guidance to suggest what will be included in either the performance assessment or composite analysis. Appropriate guidance should be included.
DOE G 435.1, IV. D	Major	The guidance states that Authorization Basis Documentation <i>should</i> be reviewed and evaluated. This is inconsistent with the general requirement which states that the authorization basis for a LLW disposal facility shall be reviewed. This statement should be changed to adequately reflect the general requirement.
DOE G 435.1, IV. D	Major	Reference is made to the Headquarters review and approval of performance assessments and composite analysis. However, the headquarters approach for review and approval is absent. Given that in DOE Order 5820.2A, the peer review panel was specifically created for this purpose and that as a part of DOE's response to the Board Recommendation 94-2 a similar DOE panel was created, the approach in DOE Order 435.1 should be made consistent with the previous approach and with commitments made in DOE's current implementation plan.
DOE G 435.1, IV. D	Major	The guidance states that, "To demonstrate compliance with the radioactive waste management basis requirement, there <i>should</i> be a documented radioactive waste management basis statement signed by the Field Office Element Manager or a designee for each LLW management facility, operation, or activity." This is inconsistent with the requirement. If the totality of documents making up the authorization basis is not technically reviewed and found adequate and a signed statement issued by the field office manager or designee, it is not credible to state that the requirement has been met. This should be changed to a mandatory requirement.

Low-Level Waste

Reference	Status	Comment
DOE M 435.1, IV.E(1)/(2)	Major	These two requirements, though sound, cannot likely be implemented in their current form. Both requirements suggest that contingency storage and transfer equipment sufficient to effect immediate transfer must exist. In other words, system reliability and availability must always be maintained at 100%. This is not consistent with the Board's staff experience in the field. This guidance should be corrected to reflect an adequate, operationally feasible approach for managing contingency storage.
DOE G 435.1, IV.E(1)	Major	The guidance states that, "Contingency storage is to be provided for both stored liquid waste and for liquid LLW treatment facilities. In the case of storage tanks, adequate volumetric capacity should be available to receive the largest volume of waste stored in a single tank." This guidance does not appear to address contingency storage and transfers if a single mode failure can impact the existing tank storage system, e.g., a seismic event adversely impacts the ability to make transfers between tanks due to pipe breaks. The guidance should clearly address single mode failures if they are applicable to the tank storage system .
DOE G 435.1, IV.E	Major	The guidance states, "Every Shift should have qualified individuals and the equipment necessary to perform transfers in a timely manner." This is not consistent with the requirement that transfer equipment shall be maintained in an operational condition at all times. If a shift does not have qualified individuals that can effect transfers, the condition, i.e., qualified individuals and the equipment necessary, is not met. The guidance should be changed to reflect the need to always have qualified individuals present who are capable of making transfers. Additionally, the measure of success cited, "timely manner" needs to be defined.
DOE G 435.1, IV.F(2)	Major	The requirement states that, "Operations shall be curtailed or facilities shut down for failure to establish, maintain, or operate consistent with an approved radioactive waste management basis." The guidance states that, "If the field element Manager determines that an operation, activity, or facility is not operating in compliance with an approved radioactive waste management basis, he or she should curtail operations or shutdown the facility, as specified in this requirement." These two statements should be made consistent since the guidance suggests that action is optional (use of the term <i>should</i> in the guidance).

Low-Level Waste

Reference	Status	Comment
DOE G 435.1, IV.G(1)	Major	The guidance states that, “The waste acceptance requirements and documentation for a facility receiving waste for storage, treatment, or disposal should be prepared using a graded approach commensurate with the hazards associated with the management of the waste in the facility and the complexity of the activities to be conducted in the facility and upon the waste.” Change this statement to reflect the current DOE policy and guidance related to integrated safety management which clearly is applicable to this discussion.
DOE G 435.1, IV. G(1)	Major	The guidance states that the performance assessment and composite analysis should be used to establish the waste acceptance criteria. This guidance should be changed to reflect that the PA and CA shall be used for this purpose.
DOE G 435.1, IV. G(1)	Major	The guidance states that, “Waste acceptance requirements should specify that wastes received at the facility should be in a physically/chemically stable form.” The guidance should establish a practical technical definition of physically/chemically stable.
DOE M 435.1, IV.G(1)(d)1	Major	This requirement states that, “Low-level waste must be packaged to achieve long-term stability of the facility....” The term, “long-term stability” must be defined to adequately develop packaging designs.
DOE G 435.1, IV.G(1)(d)2	Major	This requirement states that, “Low-level waste must not be readily capable of detonation or of explosive decomposition or reaction at anticipated pressures and temperatures , or of explosive reaction with water.” The term “readily capable” should be defined and made consistent with the guidance on page IV-40 which states that there shall be “no chance” that a detonation or explosion shall occur.

Low-Level Waste

Reference	Status	Comment
DOE G/M 435.1, IV.G(1)(d)5	Major	This requirement states, “Low-level waste in a gaseous form must be packaged such that the pressure does not exceed 1.5 atmospheres absolute at 20°C.” The guidance related to this requirement states that the intent of the requirement is to protect workers and the long term-stability of the site by specifying the maximum pressure at which gaseous radioactive waste is to be packaged. The guidance also states that, “An analysis should be conducted on any waste materials that could potentially generate gases due to conditions of storage or treatment to ensure that the pressure stated in the requirement will not be exceeded.” The guidance should address conditions inherent in the waste form that could result in gas generation. For example, spent organic ion exchange resin will generate hydrogen gas. Gas generation is not due to a condition of storage or treatment rather it is due to radiolysis of the ion exchange media. If the intent is to protect long-term stability of the disposal facility then, under what conditions the gas is generated is not relevant and the analysis should also extend to any waste form capable of gas generation.
DOE M/G 435.1, IV.G(2)	Major	The requirement states that, “The receiving facility shall evaluate waste for acceptance, including confirmation that the technical and administrative requirements have been met.” The guidance states that the process should consist of approaches that can result in a “high confidence” that the waste presented meets the acceptance requirements. This latter statement suggests that a statistical sampling method is needed to demonstrate compliance but no quantitative measure(s) is provided. If a quantitative approach is desired it should be clearly stated.
DOE G 435.1, IV.H(2)	Major	The guidance states that, “The determination of whether a low-level waste stream has an identified path to disposal should be based on the availability of existing or planned facilities and operations. A planned facility is considered to be “available” if it has been authorized (e.g., a line item in a congressional appropriation or equivalent approval for design and construction).” This guidance should be changed to reflect the technical issues which are important in determining whether a specific waste type is likely to meet a facility WAC, e.g., it is sufficiently well understood waste types will be disposed in the facility.

Low-Level Waste

Reference	Status	Comment
DOE G 435.1, IV.I	Major	The guidance states that, “characterization data that is generated during generation, storage, and after treatment of low-level waste needs to be reliable and in sufficient detail to ensure subsequent management can be conducted safely and to meet the waste acceptance requirements of all subsequent receiving facilities.” The guidance should define the criteria for determining if the data is “reliable” and in “sufficient detail”.
DOE G 435.1, IV.I	Major	The guidance states, “Characterization data should be subjected to a quality assurance program and the program that applies should be identified and documented.” What is the standard for this program?
DOE M 435.1, IV.I(1)	Major	This requirement states, “The data quality objectives process, or a comparable process, shall be used for identifying characterization parameters and acceptable uncertainty in characterization data.” The guidance for this requirement fails to establish an adequate standard for completing this process. Rather than supplying a very brief description of the EPA’s process and referencing the EPA approach, a more technically complete approach would be to cite the EPA approach as the standard (incorporate by reference).
DOE M/G 435.1, IV.I(3)	Major	This requirement states, “For indirect methods to be used, there shall be a reasonable assurance that the data resulting from indirect methods can be correlated with data resulting from measurements based on direct methods.” The use of the term “correlated” suggests mathematical precision of some degree; however, the guidance does not address any applicable methods or criteria used to address “the acceptable range of certainty and precision.” It is assumed that the data quality objectives process would be used to develop these methods and criteria for precision but this is similarly not addressed.

Low-Level Waste

Reference	Status	Comment
DOE M/G 435.1, IV.L(1)(a)	Major	This requirement states, “Low-level waste shall be packaged in a manner that provides containment and protection for the duration of the anticipated storage period and until disposal is achieved or until the waste has been removed from the packaging.” The guidance needs to address the methods used to determine “anticipated” storage period since this is the key parameter in determining containment designs. For example, in using the qualification “anticipated” with respect to the storage period storage period there appears to be the assumption that this period is well known. This is not the experience of the Board’s staff. Additionally, the guidance should include acceptable methods which can be used to qualify/quantify the storage period, e.g., a sensitivity analysis or an established standard approach for developing time of storage.
DOE G/M 435.1, IV.M(1)(c)	Major	In the DOE system LLW facility siting is based on the ability of the site to support safe operations. This is also the principle function of the performance assessment/composite analysis. However, it does not appear that these studies would be completed prior to a siting decision. The guidance should be changed to reflect that a PA should be part of the information used in making a siting decision.
DOE M 435.1, IV.M(1)(c)	Major	The specific criteria used in the screening of potential sites should be listed.
DOE M 435.1, IV. M(3)(a)	Major	The requirement states, “Low-level waste disposal facilities shall be designed to achieve long-term stability....” The term, “long-term” is not adequately defined.
DOE G 435.1, IV. M(3)(a)	Major	The guidance states, “Site design should be based on the projected waste volume and characteristics, as well as the characteristics of the site selected, so that, during the required performance period of the site, contaminant releases do not result in projected exposure above the performance objectives.” This guidance should be changed to reflect specific attributes of facility design.
DOE M/G 435.1, IV.N(1)(d)	Major	The guidance states, “Any facility that manages low-level waste packages should establish a process to implement this requirement.” This must be changed to state that facilities shall establish a process to implement this requirement.

Low-Level Waste

Reference	Status	Comment
DOE M/G 432.1, IV.P(1)	Major	The requirement uses the term “reasonable assurance” without adequate definition.
DOE G 435.1, IV.P(1)	Major	The guidance states, “The performance objectives listed in this requirement provide criteria that define the <u>desired</u> level of protection of the public and the environment from disposed low-level waste that lead to comfort level that, when actually measured sometime in the future, compliance with real protection requirements will be easily achieved.” Discrete technical guidance to establish the standards for completing a PA or CA must be included in the guidance in order to meet this objective.
DOE M 435.1, IV.P(2)	Major	The guidance states, “Consequently, detailed guidance on conducting performance assessments has been developed and is contained in <i>Format and Content Guide for U.S. Department of Energy Low-Level Waste Disposal Facility Performance Assessments and Composite Analysis</i> .” This document is not sufficiently detailed to provide adequate technical guidance for the preparation of PA’s and CA’s. The guidance should include the guides provided to the Board as part of the earlier draft of this Order.
DOE G/M 435.1, IV.P(2)	Major	The requirement states, “The point of compliance shall correspond the point of highest projected dose or concentration beyond a 100 meter buffer zone surrounding the disposed waste. A larger or smaller buffer zone may be used provided adequate justification is provided.” The guidance should specifically address what technical criteria will be used to provide “adequate justification.”
DOE M/G 435.1, IV.P(2)	Major	Since the time of compliance is 1000 years why aren’t all reasonably foreseeable future events based on that time frame. For example, the guidance says that a 100 year flood is foreseeable. Why not a 1000 year flood?
DOE G 435.1, IV.P(2)	Major	The guidance states with respect to the sensitivity/uncertainty analysis, “This calculation should be used for increasing the understanding of the models used and the disposal facility performance, and not for determining any compliance matters or conditions of operation on the facility.” Since the PA is a fundamental part of the disposal authorization basis, uncertainties associated with the models used in the PA must be reflected in facility operation. The guidance should be changed to reflect this.

Low-Level Waste

Reference	Status	Comment
DOE G 435.1, IV.P(2)	Major	The guidance states that alternate methodologies are acceptable. The standard of reasonable assurance is also cited to apply to any alternative method employed. The guidance should specifically address what technically defensible approaches are acceptable substitutes for the PA or CA.
DOE G 435.1, IV.P(2)	Major	In the reference section on page IV-158 is the interim guide for the format and content of PA's. These content from these documents should be included in the Order/Manual/Guide as it was previously intended to be.
DOE G 435.1, IV.P(3)	Major	If the point of compliance can be moved to accommodate any sized buffer area, why is there need for the composite analysis? In the example cited on page IV-153, the area adjacent to an active site contains several contaminated areas. In order to determine the size of the Buffer Area, an analysis very similar, if not identical to, the CA would be required to establish the appropriate size and controls needed to support siting and design of the facility. Why therefore is a CA also needed?
DOE G 435.1, IV.P(3)	Major	The guidance on pages IV-160-161 cites as references documents that are either draft or are interim. The information in these documents should be a part of the directive note merely referenced.
DOE G 435.1, IV.P(4)	Major	The discussion related to PA/CA maintenance does not include discussion on the research and development commitments recently made to the Board. Why are they missing?
DOE G 435.1, IV.P(4)	Major	The review guide cited on page IV-165 has not been received by the Board and reviewed by the Board's staff. Based on its apparent importance with respect to the disposal authorization statement this document needs to be provided for review.
DOE G 435.1, IV.P(6)b	Major	There should be a technical definition of "permanent."
DOE G 435.1, IV. Q(1)	Major	Why is there no format and content guide similar in scope and detail for the PA and CA's?

Low-Level Waste

Reference	Status	Comment
DOE M/G 435.1, IV.R(2)	Major	Include in the guidance technical performance specifications related to “how well” the liquid levels must be monitored, e.g., detection capability above changes due to atmospheric conditions. Additionally, technical performance specifications for monitoring chemical characteristics should be included.
DOE G 435.1, IV.R(3)	Major	The discussion in this section should include reference to technical performance criteria associated with how well the monitoring program must be to meet this requirement.